Docket No. ROC-26DIV1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Theresa Callaghan et al.	Confirmation No.: 5734
Appln. No.	:	10/721,537	
Filed	:	November 25, 2003	
Title	:	METHOD FOR THE TOPICAL TREATMENT AND PREVENTION OF INFLAMMATORY DISORDERS AND RELATED CONDITIONS USING EXTRACTS OF FEVERFEW (TANACETUM PARTHENIUM)	
Art Unit	:	1654	
Examiner	:	Susan D. Coe	

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

November 4, 2005
(Date of Deposit)

William E. McGowan
(Name of applicant, assignee, or Registered Representative)

(Signature)

November 4, 2005
(Date of Signature)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 CFR 1.132

Dear Sir:

I, Neena Tierney, declare and state that:

1. I am a citizen of the United States, residing at1081 Drew Drive, Yardley, PA 19067.

2. I have a B.S. in Chemical Engineering from Purdue University and a Ph.D. in Chemical Engineering from Princeton University.

3. I have been employed by Johnson & Johnson since October 2000. I am presently the Staff Scientist in R&D for Johnson & Johnson Consumer Companies, Inc. ("JJCC").

4. I have read the above-identified application and the Office Action dated June 24, 2005 ("Office Action").

5. I and my group at JJCC conducted a six-month clinical study for quantitative assessment of consumer benefits of the topical application to humans of of a composition containing an extract of feverfew that is substantially free of α-unstturated γ-lactone ("Feverfew Composition"). The study was conducted among 42 women (ages 35-65 with skin types I-III) using the Feverfew Composition and a placebo formulation (which contained the same ingredients but for the extract of feverfew).

We evaluated various skin benefits on the test subjects, including the compositions effect on skin tone & texture, skin lightening, eveness of pigmentation, skin renewal, and skin matrix proteins. The results showed statistically significant improvement for feverfew active versus placebo for several of these tested benefits. The results of the study are illustrated below in Table A.

Table A.

Benefits	**Feverfew Composition**	**Placebo**
Tone & texture (self assessment on improvement)	100% of subjects agreed that Feverfew improved their tone & texture***	63% of subjects agreed that Placebo improved their tone & texture
Lightness (Pixel Intensity of selected Region of Interest in UV photograph)	Pixel intensity increased (became lighter, more radiant) by 2.8 a.u. for Feverfew versus baseline*	Pixel intensity increased (became lighter, more radiant) by 1.2 a.u. for Placebo versus baseline

Evenness of Pigmentation (Standard Deviation of Pixel Intensity of selected Region of Interest in UV photograph)	Feverfew increased Evenness of pigmentation (skin tone more even, homogeneous) by 0.5 a.u. versus baseline**	Placebo *decreased* Evenness of pigmentation by 0.1 a.u. versus baseline
Skin Renewal (Trypophan Fluorescence)	Feverfew increased skin renewal 1.2 a.u. versus baseline**	Placebo increased skin renewal 0.6 a.u. versus baseline
Matrix Proteins (Fluorescence of Collagen Crosslinks)	Feverfew increased matrix proteins (collagen crosslinks) 0.05 a.u. versus baseline***	Placebo increased matrix proteins (collagen crosslinks) 0.02 a.u. versus baseline

* statistically significant versus baseline, p=0.1

** statistically significant versus placebo, p<0.1

***statistically significant versus placebo, p<0.05

Thus, the topical application to humans of the Feverfew Composition resulted in the significant improvement of various skin benefits.

6. I, Neena Tierney, further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further declare that the statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 35 USC §1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or patent issuing thereon.

By: Neena Tierney

Neena Tierney, PhD.